DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
HFA-35

60 8th Street, N.E.
Atlanta, Georgia 30309

May 13, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Joe Kelly
353 Club Road
Buchanan, Georgia 30113

WARNING LETTER

Dear Mr. Kelly:

An inspection of your operation located in Buchanan, Georgia, by a Food and Drug Administration investigator, Marie F. Mathews on April 18, 1997, confirmed a cow purchased and sold by you on or about October 22, 1996, for slaughter for human food to [redacted] was in violation of Section 402 (a)(2)(D) of the Federal Food , Drug, and Cosmetic Act.

USDA/FSIS analysis of tissues collected from that animal disclosed the presence of the drugs oxytetracycline and penicillin. Oxytetracycline was found in the kidney at 19.00 ppm and in the liver at 5.00 ppm. Penicillin was found in the liver at 0.06 ppm. A tolerance level of 00.10 ppm has been established for residues of oxytetracycline and 00.05 ppm for residues of penicillin in the edible tissues of cows, Title 21, Code of Federal Regulations, Sections 556.500 and 556.510. the presence of these drugs in edible tissue from this animal causes the food to be adulterated.

Our investigation revealed that when you purchase cattle you do not obtain written or verbal assurance from the cattle producer as to whether or not the animal has been medicated, and that the animal is free from drug residues.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

The violations listed above are not intended to be an all inclusive list. It is your responsibility to assure that your operation is in compliance with the law. As a dealer of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce, the adulterated animal. As such, you share the responsibility for violating the Federal Food, Drug and Cosmetic Act. To avoid future illegal residue violations you should take precautions such as:

1. implementing a system to identify the animals you purchase with records to establish traceability to the source of the animal;

2. implementing a system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and

3. if the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

You should be aware that it is not necessary for you to have personally shipped an animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an animal for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence.

Your reply should be directed to the address in the letterhead, attention Barbara A. Wood, Compliance Officer.

Sincerely yours,

for Roger E. Kline

Ballard H. Graham, Director
Atlanta District